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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,495

01/03/2006

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LFS-5004USNP

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EXAMINER

PANI, JOHN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

09/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,495	Applicant(s) KERMANI ET AL.	
	Examiner JOHN PANI	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/28/08, 6/17/08, and 6/20/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-17 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 4-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/20/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (Claims 19-27) in the reply filed on 6/17/2008 is acknowledged.

Claim Objections

2. Claim 19 is objected to because of the following informalities: In line 6 it is suggested to insert –and—prior to "thereby". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 19-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Line 5 of claim 19 recites "that is an indicator of dermal tissue penetration depth by the skin-piercing element." It is unclear which previous element "that" in line 5 refers to. The lack of clarity regarding the scope of the claim renders it and claims 20-27 indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 19-21 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0065481 to Cory et al. ("Cory").

8. Cory teaches:

In reference to Claim 19

A method for piercing dermal tissue (see Fig. 2 and [0049]—[0058]) comprising: contacting dermal tissue with at least one electrical outer skin pressure contact (135); and inserting a skin-piercing element (107) into the dermal tissue while measuring an electrical characteristic ("voltage") existent between the skin-piercing element and the at least one electrical outer skin pressure contact through the dermal tissue that is an indicator of dermal tissue penetration depth by the skin-piercing element, and thereby penetrating into the dermal tissue.

In reference to Claim 20

The method of claim 19 (see above) further including the step of presenting a user with an indicator of a dermal tissue penetration depth of the skin-piercing element, said indicator being based on the measured electrical characteristic (see [0058]).

In reference to Claim 21

The method of claim 19 (see above) further including the step of presenting a user with an indicator of a dermal tissue penetration stability of the skin-piercing element, said indicator being based on the measured electrical characteristic (see [0058], penetration depth is an indicator of penetration stability, because the deeper the penetration, the more difficult it is to remove the penetrating member).

In reference to Claim 26

The method of claim 19 (see above) wherein the measuring is accomplished by applying a current in the range of 1 mA to 10 mA (see [0048]).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 19 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0083641 to Angel et al. ("Angel") in view of Cory.

In reference to Claims 19 and 23

Angel teaches a method for piercing dermal tissue comprising: contacting a dermal tissue (see [0045]) with at least one electrical contact (**14**); and inserting a skin-piercing element that is a microneedle (a second microneedle **14**) into the dermal tissue while measuring an electrical characteristic (impedance) existent between the skin-

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piercing element (**14**) and the at least one electrical contact (a second microneedle **14**) through the dermal tissue that is an indicator of dermal tissue penetration depth by the skin-piercing element, thereby penetrating the dermal tissue (see [0045]). However, Angel does not teach that the dermal tissue is contacted with an outer skin pressure contact.

Cory teaches a method comprising: contacting dermal tissue with at least one electrical outer skin pressure contact (135); and inserting a skin-piercing element (107) into the dermal tissue while measuring an electrical characteristic ("voltage") existent between the skin-piercing element and the at least one electrical outer skin pressure contact through the dermal tissue that is an indicator of dermal tissue penetration depth by the skin-piercing element, and thereby penetrating into the dermal tissue.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method of Angel by including a reference electrode which rested on the surface of the skin, and modifying the penetration members to be similar to those taught by Cory, as this would allow for a numerical value of the needle penetration depth to be calculated and outputted, thereby increasing accuracy over Angel.

In reference to Claim 22

Angel in view of Cory teaches the method of claim 19 (see above) and Angel further teaches the step of presenting a user with an indicator of a dermal tissue penetration residence time (see Fig. 9A of the skin-piercing element. Impedance is greatest before penetration and higher after penetration has begun. See also [0096])

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said indicator being based on the measured electrical characteristic (measured impedance).

In reference to Claim 24

Angel in view of Cory teaches the method of claim 19 (see above) and Angel further teaches the inserting step includes inserting (see [0045]) a micro-needle (**14**) of an integrated (see Fig. 2A) micro-needle and biosensor medical device (Reservoir **46** can contain a reagent for causing a reaction, i.e. to act as a biosensor, or additionally, see [0098]).

In reference to Claim 25

Angel in view of Cory teaches the method of claim 19 (see above) and Angel further teaches inserting step further involves measuring the electrical characteristic (impedance) prior to contact between the skin-piercing element (**14**) and the dermal tissue, when the skin-piercing element has contacted the dermal tissue, and when the skin-piercing element has penetrated the dermal tissue (see [0096]).

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Angel in view of Cory as applied to claim 19 above, and further in view of US Pat. No. 5,069,223 to McRae ("McRae").

Angel in view of Cory teaches the method of claim 19 (see above), but does not mention the frequency range of the applied potential. McRae teaches of a method for measuring the impedance of tissue in which impedance is measured by applying a potential in a frequency range of 10KHz to 30MHz (col. 3 lines 1-20).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an applied potential of 10KHz to 30 KHz for measuring in the device of Angel, because this range is known to be appropriate for application to skin, as implicitly taught by McRae.

Response to Arguments

11. Applicant's arguments filed 1/28/2008 have been fully considered but they are not persuasive. In reference to Applicant's assertion that Cory does not teach "measuring an electrical characteristic existent between a skin-piercing element and electrical outer skin pressure contacts through the dermal tissue," the Examiner respectfully disagrees, because while (as noted by Applicant) Cory does teach calculating the resistance (R_a) of a needle coating protruding above a surface, Cory further teaches (" R_a is calculated directly from the ratio of the measured voltage to the applied current") that this resistance is calculated based on a voltage measured between the needle 107 and return electrode 135 (see [0052] and [0055]).

12. Applicant's other arguments with respect to claims 19-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JP 9/22/08

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736